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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,875	08/25/2003	Xiugao Liao	40757.0510258	3179

26874 7590 06/09/2005

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EXAMINER

DANIELS, MATTHEW J

ART UNIT PAPER NUMBER

1732

DATE MAILED: 06/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/647,875	<b>Applicant(s)</b> LIAO ET AL.	
	<b>Examiner</b> Matthew J. Daniels	<b>Art Unit</b> 1732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/20/03</u> . | 6) <input type="checkbox"/> Other: _____  |

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## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. **Claims 1, 27, 28** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **As to Claim 1**, the Applicant's step c) in Claim 1 defines the invention by stating that the extracted lens has no change in transparency in aqueous medium. However, it is unclear if placement in aqueous medium is actually performed, rendering the claim indefinite. **As to Claims 27 and 28**, it is unclear if a step of soaking in aqueous medium is actually being performed.

2. **Claim 13** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is rejected specifically for the portion which reads "other alkyl acrylates and their derivatives, and other alkyl methacrylates and their derivatives." Although a genus may be claimed, the language of this claim does not distinctly set forth what is sought. It is particularly unclear what is meant by derivatives of these substances.

3. **Claims 18 and 19** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Particularly, it is unclear whether the hydrophobic acrylic

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polymer having a molecular weight of at least about 1 million is placed into the mold and molded, or whether this represents the molecular weight after the molding process. The Applicant should clearly indicate for the record at which point in the process the molecular weight is 1 million or 10 million, as sought respectively in Claims 18 and 19.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **Claims 1-11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Liao (USPN 6271281) in view of Merrill (USPN 3916033). **As to Claim 1**, Liao teaches forming an opthamalic lens (1:19-20) from a hydrophobic (8:28-45) acrylic polymer composition (10:18-20) comprising the steps of: a) forming a prepolymer gel from a hydrophobic acrylic polymer (15:55-68), b) forming at least the optical portion of the lens from the pre-polymer gel in a glass mold (10:5). Liao appears to be silent to a fused silica mold and to step c). However, Merrill teaches a fused silica mold (9:58-68). As to step c), it would have been inherent that the extracted lens would have remained transparent in order to be used as a corneal overlay or phakic refractive lens (1:18-20). Lenses having lower transmission values would not have been suitable for their intended purpose in the method of Liao, and therefore they (the lenses of Liao) must have inherently or obviously met this limitation. It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to incorporate the method of Merrill into

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that of Liao in order to cause the material of Liao to assume the exact geometrical shapes imposed by the curved optical surfaces of the molds of Merrill (9:63-68) and allow curing by radiation (10:1-6). **As to Claim 2**, Liao teaches an intraocular lens (1:18). **As to Claim 3**, Liao teaches a phakic refractive lens (1:19). **As to Claim 4**, Liao teaches a cornea lens (1:19). **As to Claim 5**, Liao teaches a hydrophobic acrylic polymer that is a crosslinked homopolymer (6:55-7:35). **As to Claim 6**, Liao teaches a homopolymer that comprises a monomer selected from phenoxyethylacrylate, poly(ethyleneglycol) phenylethylacrylate, 2-phenylethylacrylate (6:55-60). **As to Claim 7**, Liao teaches at least one crosslinker (6:61). **As to Claim 8**, Liao teaches a crosslinker containing a rigid structure group (6:61-67). **As to Claim 9**, Liao teaches the applicant's claimed crosslinker (6:61-67). **As to Claim 10**, Liao teaches a homopolymer that contains a UV absorber (9:42). **As to Claim 11**, Liao teaches the UV absorber is 2-(4-benzoyl-3-hydroxyphenoxy)ethyl acetate (10:34-35 and 9:42).

5. **Claims 12-17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Liao (USPN 6271281) in view of Merrill (USPN 3916033), and further in view of Freeman (USPN 5693095). Liao and Merrill teach the subject matter of Claim 1. See the rejection of Claim 1 under 35 USC 103(a). **As to Claim 12**, Liao and Merrill are silent to a copolymer. However, Freeman teaches a hydrophobic acrylic polymer that is a crosslinked copolymer (2:16-38 and 2:65-68). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to incorporate the method of Freeman into that of Liao in order to provide an intraocular lens that is substantially free of glistenings (2:4-8). **As to Claim 13**, Freeman teaches a copolymer comprised of 2-phenylethylacrylate (2:37-38). **As to Claim 14**, Freeman teaches at

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least one crosslinker (1:63-65). **As to Claim 15**, Liao teaches at least bisphenol A ethoxylate (2EO/phenol) (10:33-34). **As to Claim 16**, Liao (9:41) and Freeman (1:64-65) teach that a UV absorber. Freeman teaches a copolymer. See the rejection of Claim 13. **As to Claim 17**, Liao teaches a UV absorber of 2-(4-benzoyl-3-hydroxyphenoxy)ethyl acetate (10:34-35).

6. **Claim 18** is rejected under 35 U.S.C. 103(a) as being unpatentable over Liao (USPN 6271281) in view of Merrill (USPN 3916033) and Cuffe (USPN 4102567). **As to Claim 18**, Liao teaches a method for forming a pre-polymer gel for molding of an ophthalmic lens (1:19-20) made from a hydrophobic acrylic polymer composition (15:55-68)) and comprising a) forming the pre-polymer gel which comprises a hydrophobic acrylic polymer, and b) molding the polymer (10:5-7). Liao is silent to molding the polymer to form the lens and the average molecular weight. However, Merrill teaches molding a polymer to form a lens (9:58-68) and Cuffe teaches acrylates similar to those of Liao characterized by very high molecular weights of at least 1 million (10:47-54) and almost complete freedom from strain (Abstract). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to incorporate the methods of Merrill and Cuffe into that of Liao in order to cause the material of Liao to assume the exact geometrical shapes imposed by the curved optical surfaces of the molds of Merrill (9:63-68), allow curing by radiation (Merrill, 10:1-6), and to produce implant lenses free from strain and warpage (Cuffe, 1:56-17).

7. **Claim 19** is rejected under 35 U.S.C. 103(a) as being unpatentable over Liao (USPN 6271281) in view of Merrill (USPN 3916033), Cuffe (USPN 4102567), and further in view of

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Bowers (USPN 5648442). Liao, Merrill, and Cuffe teach the subject matter of Claim 18. **As to Claim 19**, Cuffe clearly suggests to produce higher molecular weights for implant lenses (10:34-37), but is silent to 10 million. This appears to be an article limitation directed to the desired molecular weight in the lens after molding. However, Bowers also teaches a molecular weight of 10 million (27:39-47). It would have been prima facie obvious to combine the method of Bowers into that of Liao and Cuffe in order to avoid deposit formation by absorption of tears or proteins (1:14-35).

8. **Claims 20, 23, and 24** is rejected under 35 U.S.C. 103(a) as being unpatentable over Liao (USPN 6271281) in view of Merrill (USPN 3916033). **As to Claim 20**, Liao teaches a method of forming at least an optical portion of an ophthalmic lens (1:19-20) from a hydrophobic (8:28-45) acrylic polymer composition (10:18-20) by molding (10:5). Liao is silent to the molding in a fused silica mold. However, Merrill teaches a fused silica mold (9:58-68). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to incorporate the method of Merrill into that of Liao in order to cause the material of Liao to assume the exact geometrical shapes imposed by the curved optical surfaces of the molds of Merrill (9:63-68) and allow curing by radiation (10:1-6). **As to Claim 23**, Liao teaches a crosslinked homopolymer (1:11-15). **As to Claim 24**, Liao teaches a homopolymer further containing a UV absorber (9:41).

9. **Claims 21 and 22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Liao (USPN 6271281) in view of Merrill (USPN 3916033), and further in view of Liao (USPN

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6036891). Liao and Merrill teach the subject matter of Claim 20. See the rejection of Claim 20 under 35 USC 103(a). **As to Claim 21**, Liao and Merrill are silent to a treatment to form a thin coating on its surface. However, Liao ('891) teaches copolymers polymerized in an ampoule which had been pretreated with a mold releasing agent (7:55-8:13). It would have been prima facie obvious to incorporate the method of Liao ('891) into that of Liao and Merrill in order to help release the polymerized copolymer from the mold. **As to Claim 22**, Liao ('891) teaches trimethylchlorosilane (8:1).

10. **Claims 25 and 26** are rejected under 35 U.S.C. 103(a) as being unpatentable over Liao (USPN 6271281) in view of Merrill (USPN 3916033), and further in view of Freeman (USPN 5693095). Liao and Merrill teach the subject matter of Claim 20. See the rejection of Claim 20 under 35 USC 103(a). **As to Claim 25**, Liao is silent to a copolymer. However, Freeman teaches a hydrophobic acrylic polymer that is a crosslinked copolymer (2:16-38 and 2:65-68). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to incorporate the method of Freeman into that of Liao in order to provide an intraocular lens that is substantially free of glistenings (2:4-8). **As to Claim 26**, Liao (9:41) and Freeman (1:64-65) teach that the copolymer contains a UV absorber.

11. **Claims 27-31, 33-36** are rejected under 35 U.S.C. 103(a) as being unpatentable over Liao (USPN 6271281) in view of Merrill (USPN 3916033), and further in view of Freeman (USPN 5693095). Liao and Merrill teach the subject matter of Claim 1. See the rejection of Claim 1 under 35 USC 103(a). **As to Claim 27**, Liao teaches an organic solvent extraction (10:20) and



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soaking for 48 hours (10:20), but appears to be silent to the aqueous medium, 72 hours, and the temperature. However, Freeman teaches the average physiologic temperature is about 37 degrees C (4:20-25), that soaking occurs for 7+/- 1 days, and an aqueous medium (4:34-41). Freeman's teaching would have rendered the Applicant's claim to 72 hours (3 days) because Freeman teaches 6-8 days, and one of ordinary skill would have expected little to no change in the additional 3 days taught by Freeman. It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to incorporate the method of Freeman into that of Liao and Merrill in order to provide an intraocular lens that is substantially free of glistenings (2:4-8). **As to Claim 28**, this claim appears to claim an article limitation. Method claims are distinguished from other methods by method limitations, and therefore the particular transmission does not distinguish the Applicant's method from the prior art. However, although the cited references are silent to 80% transmission after soaking and drying, the Examiner's position is that the method of Liao, Merrill, and Freeman would have produced the same article, and thus it would have had the same transmission as that of the Applicant's article. Furthermore, the articles taught individually by Liao and Freeman, or suggested by the combined method of Liao, Merrill, and Freeman would not have been suitable for use as lenses if their transmission was not obviously or inherently greater than 80%. **As to Claim 29**, Freeman teaches a method that produces articles that are substantially free of glistenings (4:17-33). **As to Claim 30**, Liao teaches a method in which the extracted lens is subsequently dried at a temperature below the boiling temperature of the organic solvent used for extraction (10:23). **As to Claim 31**, Liao teaches isopropyl alcohol (10:20). **As to Claim 33**, Liao teaches a crosslinked homopolymer

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(9:22-49). **As to Claim 34**, Liao teaches a UV absorber (9:41). **As to Claim 35**, Freeman teaches a crosslinked copolymer (2:12-67). **As to Claim 36**, Liao teaches a UV absorber (9:41).

12. **Claim 32** is rejected under 35 U.S.C. 103(a) as being unpatentable over Liao (USPN 6271281) in view of Merrill (USPN 3916033), Freeman (USPN 5693095), and further in view of Mueller (4423099). Liao, Merrill, and Freeman teach the subject matter of Claim 31. See the rejection of Claim 31 above under 35 USC 103(a). **As to Claim 32**, Liao, Merrill, and Freeman are silent to ethyl alcohol. However, Mueller teaches ethanol (also known as ethyl alcohol) as a good swelling agent (12:15-23). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to incorporate the method of Mueller into that of Liao, Merrill, and Freeman in order to provide improved in situ drug therapy or removal of extractable impurities.

### ***Conclusion***

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Examiner cites Kindt-Larsen (USPN 4889664) and Weinberg (USPN 3171869) for indication of the state of the art at the time of the invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Daniels whose telephone number is (571) 272-2450. The examiner can normally be reached on Monday - Friday, 8:00 am - 5:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Colaianni can be reached on (571) 272-1196. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MJD 5/26/05



**MICHAEL P. COLAIANNI**  
**SUPERVISORY PATENT EXAMINER**